REMARKS

The applicants appreciate the Examiner's thorough examination of the application and request reexamination and reconsideration of the application in view of the preceding amendments and the following remarks.

THE EXAMINER'S 112, 2ND PARAGRAPH REJECTIONS

The Examiner rejects claims 1-18 under 35 U.S.C. §112, 2nd paragraph. The Examiner states that from the claim language it cannot be clearly determined if the applicants intend the culture medium and sample to be considered as positively recited elements of the claimed device. The Examiner also states that the claim language regarding a bio-sensor sealed in the vessel needs clarification and/or correction. The Examiner states that it appears from the applicants' remarks that applicants intend to claim a "sealed vessel", and that the claim states merely that the bio-sensor is sealed in the vessel. The Examiner states that this language could be interpreted to include a bio-sensor sealed with respect to a bottom or side wall of a vessel while the vessel still includes a top opening that is not sealed. The Examiner further states that the term "smart" renders the claims indefinite, stating that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The applicants have cancelled claims 1-18 and added new claims 19-37 to more clearly define the invention. No new matter has been added. See, e.g. the applicants' Fig. 1A and page 6, line 17 through page 7, line 7 of the applicants' specification. No new search is needed because the Examiner has searched such systems.

Claim 19 now recites, *inter alia*, a bio-sensor permanently residing in the vessel. The bio-

sensor has a coating for attracting at least one pathogen expected in a sample. There is a seal for sealing the bio-sensor in the vessel during testing of the sample. In this way, the vessel includes a bio-sensor and culture therein and all that has to be added is the sample to be tested. Monitoring by the detection circuit does not require the sealed vessel with the culture and added sample therein to be opened or disturbed.

THE CITED REFERENCES DO NOT DISCLOSE, TEACH OR SUGGEST THE APPLICANTS' CLAIMED INVENTION

The Examiner rejects claims 1 and 4-15, 17 and 18 under 35 U.S.C. §102(b) as being anticipated by *Park et al. Biosensors and Bioelectronics, Vol. 13* (hereinafter *Park et al. Vol. 13*). The Examiner also rejects dependent claim 16 under 35 U.S.C. §103(a) as being unpatentable over *Park et al. Vol. 13*. In support of these rejections, the Examiner states in pertinent part that *Park et al. Vol. 13* discloses that the bio-sensor is held within a "dip holder with a plug". The Examiner interprets this phrase to mean that the bio-sensor is held within the vessel in a sealed manner provided by the plug sealing the top opening of the vessel.

However, the Examiner's interpretation of *Park et al.* is not correct. *Park et al. Vol. 13* discloses a crystal dipped into a reaction cell. The "plug" does not provide sealing, but rather refers to an electrical plug for connection with an oscillator module.

Park et al. Vol. 13 does not disclose sealing at all. *Park et al. Vol. 13* discloses a piezoelectric quartz wafer placed between two electrodes, resulting in a crystal with a fundamental resonant frequency. Rather than disclosing a vessel including a seal for sealing the bio-sensor in the vessel during testing, the crystal disclosed by *Park et al. Vol. 13*, which functions as a working electrode, is dipped into a reaction cell. See *Park et al. Vol. 13* section

2.2. Dipping implies momentary or partial immersion. The applicant submits that this reading of dipping is borne out in *Park et al. Vol. 13*, section 2.5 (with emphasis added):

> The crystal coated with the anti-*Salmonella* antibody was dipped into a reaction cell ... For regeneration experiment, a small aliquot of 8 M urea was added onto the gold electrode for 2 min to remove adsorbed bacterial cells after one assay. The crystal was washed consecutively with the above buffer and water. It was then placed in the cell and used repeatedly.

The applicant submits that the dip holder with a plug disclosed by *Park et al. Vol. 13* is a holder to dip the electrode. See also *Park et al. Vol. 13*, Fig. 1, where it states that "[t]he arrow indicates a detailed drawing of the dip holder sandwiching the crystal". The plug of *Park et al. Vol. 13* refers to an electrical plug for connection with an oscillator module. As stated by *Park et al. Vol. 13* in section 2.2.:

> The resulting crystal ... was mounted in a dip holder with a plug and was connected with an oscillator module and a quartz crystal analyzer ...

Thus, the device disclosed in *Park et al. Vol. 13* is in sharp contrast to the applicants' claimed invention where, *inter alia*, the bio-sensor permanently resides in the vessel.

Numerous disadvantages are overcome by the applicant's claimed invention. The applicant's claimed invention allows continuous monitoring and instant detection of a pathogen in a culture medium, without the need to draw samples for testing. There is no need to remove the bio-sensor, to add solutions to the vessel during monitoring, or to contact the bio-sensor to other agents. Additionally, the applicants' claimed system decreases the chance of contamination of the sample to be tested, or contamination of the outside environment by the sample contents, resulting in greater accuracy and increased safety.

In summary, the applicants' claimed invention offers an improvement over known systems by providing speed, accuracy, safety and convenience, the combination of which was

previously lacking.

Accordingly, independent claim 19 is in condition for allowance. Claims 20-37 depend directly or indirectly from independent claim 19 (including claims 22-36 which include the elements of former claims 4-18), and thus are also in condition for allowance for at least the foregoing reason.

The Examiner also rejects (former) dependent claims 2 and 3 under 35 U.S.C. 103(a) as being unpatentable over *Park et al. Vol. 13* in view of EP 0215669 to *Karube et al.* Claims 20-21, which contain the elements of former claims 2 and 3, depend directly or indirectly from independent claim 19, and thus are also in condition for allowance for at least the foregoing reasons.

THE PRIOR ART MADE OF RECORD DOES NOT DISCLOSE, TEACH OR SUGGEST THE APPLICANTS' CLAIMED INVENTION

The *Park et al.* (Biosensors and Bioelectronics, Vol. 15) Reference

The Examiner cites *Park et al. (Biosensors and Bioelectronics, Vol. 15)* as prior art similar to that of the reference *Park et al. Vol. 13*.

Park et al. (Biosensors and Bioelectronics Vol. 15) does not add elements to *Park et al. Vol. 13* so as to disclose, teach or suggest the applicants' claimed invention.

The *He et al.* Reference

The Examiner states that the reference *He et al.* is cited as prior art that pertains to a bio-sensor that is sealed within the vessel, indicating Fig. 1 *of He et al.* The Examiner admits that *He et al.* does not disclose that the bio-sensor includes a coating for attracting at least one pathogen.

As discussed below, in addition to the failure of *He et al.* to teach a bio-sensor including a coating for attracting at least one pathogen, *He at al.* in fact teaches away from such a system. Also, the applicant submits that *He et al.* does not disclose a seal or sealing.

He et al. teaches away from a bio-sensor including a coating for attracting at least one pathogen. *He et al.* discusses a system where anti-E antibody was immobilized on the surface of a crystal and the piezoelectric resonant frequency shift due to the mass change caused by specific binding of the microorganisms to the surface is measured. However, *He et al.* then teaches away from such a system by teaching a system that relies on the fact that metabolizing bacteria change the chemical composition of the growth medium. The chemical changes cause an alteration in the impedance of the medium, and the total impedance alteration represents changes in conductance and permittivity of the medium. See, e.g. the *He et al.* Introduction.

Thus, *He et al.* discloses an entirely different system than the applicants' claimed invention, and further, teaches away from the applicants' claimed bio-sensor including a coating for attracting at least one pathogen.

Moreover, nowhere in the text of the article does *He et al.* disclose that any part of the device is sealed or that the system includes sealing in any respect. *He et al.* discloses that a quartz disc and a metal disc are fixed to the top and end of two tubes of the same central axis. Therefore, the applicants submit that the complete lack of discussion regarding any seal or sealing, combined with the discussion of a common central axis, is conclusive evidence that the unnumbered element in Fig. 1 of *He et al.* simply holds the ground glass tube 4 in place such that the platinum disc 2 has the same central axis as the electrode 3 plated on the quartz crystal 1. See e.g. *He et al.* section 2.3 and Fig. 1.

Thus, *He et al.* does not disclose each and every element of the applicants' claimed

combination, and *He et al.* teaches away from the applicants' claimed combination of elements.

Identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. In re Kotzab, 217 F. 3d 1365, 1370, 55 USPQ2d 1313, 1316 (Fed.Cir. 2000).

The law is further clear that the teaching of the desirability of combining the references must not come from the applicant's invention. "There must be a reason or suggestion in the art for selecting the procedure used, *other* than the knowledge learned from the applicants' disclosure." See In re Dow Chemical Company, 837 F. 2d 469,473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1989) (with emphasis added).

Thus, for the foregoing reasons, *He et al.* is in sharp contrast to the applicant's claimed invention.

CONCLUSION

Accordingly, claims 1-17 and 19-21 are in condition for allowance.

Each of Examiner's have been addressed or traversed. Early and favorable action is respectfully requested.

If for any reason this Response is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the

undersigned or his associates, collect in Waltham, Massachusetts at (781) 890-5678.

Respectfully submitted,

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